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April 27, 2004
Suture Arrow
510(k) # K041128

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Suture Arrow 510(k) Number _____.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Elizabeth M. Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: Suture Arrow

Common Name: Meniscal Repair Device

Classification Names: Orthopedic

Proposed Class/Device: Class II

Product Code MAI, GAT

D. Predicate/Legally Marketed Devices

Arthrex Meniscal Dart System	510(k) # K983577
Contour Meniscus Arrow	510(k) # K012334

E. Device Description

The Suture Arrow is a sterile, single-use, meniscal repair device, which consists of two bioabsorbable, implantable arrow-like device (hereafter referred to as "arrows"), one smooth (primary) and one barbed (secondary) joined by a suture. The primary "arrow" has a smooth surface for lateral penetration through the meniscus. The secondary "arrow" is covered with 4 circumferentially spaced rows of 3 barbs each. The barbs in each row are spaced longitudinally over the surface. The barbs are designed to anchor the secondary "arrow" implant in the meniscal tissue thereby reducing the possibility of loosening and migration of the implant.

The "arrows" are pre-threaded with a single strand of braided USP #0 non-absorbable polyester suture. The suture is immovably attached to each "arrow" by inserting the suture through an eyelet on each "arrow" and knotting the suture. The implant has different suture lengths: 16mm and 20mm. A trailing end of suture is provided to aid in the manipulation of the implant. The implant is designed to permit an all inside meniscal repair to reduce the risk of injury to the posteromedial and posterolateral neurovascular knee structures. The "arrows" are made from a copolymer derived from poly-80L/20D, L-lactide. When properly used, in the presence of adequate immobilization, the implant maintains proper fixation of the meniscal tear. As the tear of the meniscus heals, the "arrows" gradually lose strength over 20 - 35 weeks *in vivo* (depending on patient variables). Complete biodegradation and chemical resorption of the "arrows" may take a few years post-operatively. The Suture Arrow implant is sterile, inert and non-collagenous.

Teleflex Inc.,600 Airport Road, Fall River, MA 02720, USA, supplies the suture.

The Suture Arrow implant is inserted into the tissue using a sterile, single-patient use, disposable instrument, the Arrow Inserter. The Arrow Inserter is designed to deliver each "arrow" at the appropriate site in the tissue.

The Inserter handle is made of an injection-molded polycarbonate and contains internal components made from injection molded polycarbonate and 20% glass-filled polypropylene. The handle is affixed to a stainless steel cannulated needle. The cannulated needle can be manipulated to facilitate precise positioning of the "arrows" at the tip of the needle for precise delivery into the tissue. The tip of the needle is beveled, angled and sharpened for penetration into the meniscus. There are two sets of depth markers on the cannulated needle. The proximal-most set are positioned at 19mm, 24mm, 29mm and 34 mm from the tip to facilitate placement of the distal "arrow". The markers of the distal-most set are positioned at 6mm, 8mm and 10mm from the tip to facilitate placement of the secondary "arrow".

To prepare the Inserter for loading, the white release button on the handle is depressed to allow the user to move the cannulated needle to the open position. The open position allows the slot on the cannulated needle to be exposed. Opening the cannulated needle enables the user to insert the implant into the slot of the needle. The implant is placed into the slot with the primary and secondary "arrows" lined up behind one another. Depressing the white button again closes the cannulated needle and moves the primary "arrow" from the slot to the tip for delivery while simultaneously advancing the secondary "arrow" forward. The Arrow Inserter is positioned in the meniscus so the first "arrow" can be deployed on the exterior of the meniscus by pulling back the black finger tab to retract the cannulated needle. The needle is then removed from the meniscus and the tip is positioned for deploying the secondary "arrow" though the tear. The secondary "arrow" is positioned in the cannulated needle by depressing the white release button. The secondary "arrow" is then deployed by pulling back the black finger tab again. Repair of a meniscal tear may require more than one Suture Arrow implant. The process is repeated for additional implants.

The Suture Arrow must be loaded on the Arrow Inserter. To facilitate loading, the Suture Arrow implant is supplied on a disposable,

polycarbonate loader. The Arrow Inserter is supplied with a sterile peel-away protective sleeve to protect surrounding tissue from the sharp tip of the cannulated needle. The Inserter can be manipulated into position with the protective sleeve which can be peeled off when it is not needed. The Arrow Inserter and the protective sleeve can be used multiple times on a single patient.

A non-sterile, reusable, stainless steel knot pusher is also available to push the secondary arrow deeper in the meniscal tissue and tighten the suture if necessary.

F. Intended Use

The Suture Arrow implant is indicated for use in repairs of knee meniscus tears that would otherwise be considered for standard repair using suture.

G. Substantial Equivalence

The Suture Arrow implant is substantially equivalent in design and intended use to the Arthrex Meniscal Dart System (K983577) – Arthrex Inc.

The Suture Arrow inplant is substantially equivalent in materials to the Contour Meniscus Arrow (K012334) – Bionx Implants Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

Ms. Elizabeth M. Paul
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K041128
Trade/Device Name: Suture Arrow
Regulation Numbers: Unclassified, 21 CFR 878.5000
Regulation Name: Fastener, fixation, biodegradable, soft tissue; Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulatory Class: II
Product Codes: MAI, GAT
Dated: April 27, 2004
Received: April 30, 2004

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

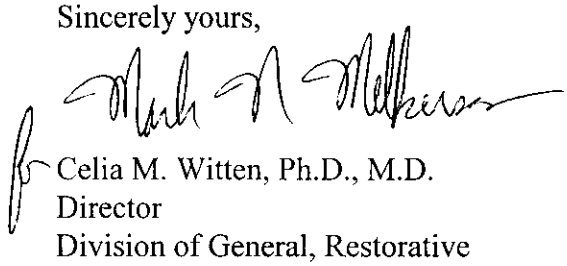
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

April 27, 2004

510(k) Number (if known): K041128

Device Name: Suture Arrow

Indications for Use:

The Suture Arrow is indicated for use in repairs of knee meniscus tears that would otherwise be considered for standard repair using suture.

Prescription Use X OR Over-the-Counter Use__
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Millhouse

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041128